

### REMARKS

Claims 1-68 are the pending claims in the present application, and claims 63-68 are currently under consideration. Applicants will cancel non-elected claims upon indication of allowable subject matter. Please cancel, without prejudice, claim 64. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to demonstrate that applicants had possession of the claimed invention. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

Applicants contend that the term "bioactive fragment of a hedgehog protein" is sufficiently described in the specification to demonstrate to one of skill in the art that applicants were in possession of the claimed invention (see, for example, page 9, lines 24-26). The application further provides examples of bioactive fragments of hedgehog proteins, as well as functional characteristics that help determine if a fragment is a bioactive fragment. Such functional characteristics include the ability to bind to a patched protein and the ability to promote hedgehog signal transduction. Applicants' description of exemplary bioactive fragments based on both structure and function refutes the allegation made in the previous Office Action that the application merely describes a "bioactive fragment" based on what it does.

Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claim 63 to more explicitly point out certain embodiments of the invention. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are requested.

2. Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

As outlined in detail in section 1 of this response, Applicants contend that the application provides ample support to clearly describe and define the term “bioactive fragment of a hedgehog protein.” Accordingly, one of skill in the art could readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claim 63 to more particularly point out certain embodiments of the invention. Applicants’ amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are requested.

3. Claims 63 and 68 are rejected under 35 U.S.C. 102 (a) as allegedly being anticipated by Ingham et al. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

Ingham et al. fail to satisfy the criteria for anticipating Applicants’ invention. Both the MPEP and the Federal Circuit support Applicants’ contention that in order to anticipate or render obvious the claimed invention, the cited art must teach all the limitations of the claimed subject matter (MPEP 2131). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

*Verdegall Bros. v. Union Oil Company of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the .... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ3d 1913, 1920 (Fed. Cir. 1989). The Ingham et al. application fails to teach the particular combination of elements of the pending claims.

Nor is the claimed subject matter obvious in view of the teachings of Ingham et al. Applicants contend that a valid patent may issue for a nonobvious species related to a prior patented invention, even though the improvement falls within the claims of that prior patent. A prior genus which does not explicitly disclose a species does not anticipate a later claim to that species. This position is well supported by the holdings of the Federal Circuit. See, for example, *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1262, 9 USPQ2d 1962, 1970 (Fed. Cir. 1989).

Applicants contend that the relationship between the pending claims and the cited art is largely analogous to the factual situation in the above example. Applicants assert that the presently claimed invention is a species which is unobvious and patentable over the generic teachings of Ingham et al.

Applicants contend that Ingham et al. fail to teach or suggest all the limitations set forth in the claims. Although Ingham et al. is broadly enabling and provides compositions and methods using *hedgehog* polypeptides, Ingham et al. fail to teach the benefits of the particular combination of agents and mode of administration set forth in the pending claims. That is, although Ingham et al. broadly teach methods using *hedgehog* polypeptides, Ingham et al. provide no motivation to specifically select the particular preparation presently claimed. MPEP 2144.08 outlines the guidelines for determining that a reference renders an invention obvious and directs the Examiner to "determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus." Applicants contend that Ingham et al. fail to provide motivation to select the particular preparation for topical application to skin or hair, as required by the claims.

Applicants maintain that Ingham et al. fail to satisfy the criteria necessary for anticipating or rendering obvious Applicants' invention. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same

and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

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Respectfully Submitted,



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